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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE SERIAL NUMBER <u>2200020</u>54420 NOONBERG 08/324,001 10/13/94 MARTINELL, J 18M1/1206 **ART UNIT** PAPER NUMBER MORRISON & FOERSTER 755 PAGE MILL ROAD PALO ALTO CA 94304-1018 1804 DATE MAILED: 12/06/95 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS Responsive to communication filed on 7/5/45 This action is made final. This application has been examined _ month(s), ____ A shortened statutory period for response to this action is set to expire ____ __days from the date of this letter. Fallure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 2. Notice of Draftsman's Patent Drawing Review, PTO-948. 1. Notice of References Cited by Examiner, PTO-892. 3. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, PTO-152. 6. NOTTREE TO COMPLY WITH 5. Information on How to Effect Drawing Changes, PTO-1474... SENUCALE RYLES Part II SUMMARY OF ACTION 1-28 are pending in the application. 1. X Claims____ are withdrawn from consideration. Of the above, claims _ 2. Claims_ have been cancelled. 3. Claims ___ 4. X Claims 1-28 _ are objected to. 5. Claims are subject to restriction or election requirement. 7. A This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. 9. The corrected or substitute drawings have been received on _ are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). 10. The proposed additional or substitute sheet(s) of drawings, filed on _ _____, has (have) been approved by the examiner: \square disapproved by the examiner (see explanation). ____, has been approved; disapproved (see explanation). 11. The proposed drawing correction, filed ____ 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on ____ 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

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This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The disclosure is objected to because of the following informalities.

- (a) The blank at page 43, line 21 is improper.
- (b) The material in brackets at page 44, lines 16-21 is not understood.
- (c) The material in brackets at page 45, line 20 is not understood.

Appropriate correction is required.

The instant application does not contain a Sequence Listing as is required under 37 CFR §§ 1.821 - 1.825. Accordingly, a Sequence Listing is required for applicant's response to this office action to be complete. Sequences are mentioned in at least the following locations in the instant application:

- (a) page 51,
- (b) page 68,
- (c) page 89,
- (d) claim 16,
- (e) claim 17,
- (f) claim 26,
- (g) Figure 2,
- (h) Figure 3,
- (i) Figure 9,

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- (j) Figure 10,
- (k) Figure 24, and
- (I) Figure 27.

Claims 1-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "stabilizing region" (claims 1, 3, and 4) is vague and indefinite because the characteristics of the stabilizing region are not mentioned.
- (b) The recitation of "U6-type" (claims 2, 3, 7, 8, 15, 21, and 24) is vague and indefinite because the metes and bounds of the claims are not clear. The amount of variation is a U6-type sequence is not known or mentioned.
- (c) Claims 16, 17, and 26 are incomplete because the sequences recited in these claims are not identified by SEQ ID NOs. Applicant's attention is directed to 37 CFR §§ 1.821 1.825 and MPEP 2422 2433.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by either one of Jennings et al or Sullenger et al. Each of the references teaches the control of an

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antisense molecule by using a vector in which the antisense sequence is under the control of an RNA polymerase III promoter.

Claims 27 and 28 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Noonberg et al (BioTechniques 16: 1070 (June 1994)). The instant claims do not find basis in parent application Serial No. 08/138,666.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 305-3014. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1804.

Claims 2-26 are rejected under 35 U.S.C. § 103 as being unpatentable over either one of Jennings et al or Sullenger et al in view of applicants' admitted state of the prior art (e.g., instant application at page 25, lines 15-24). Each of Jennings et al and Sullenger et al teaches the construction of vectors that produce oligonucleotides that are flanked by RNA polymerase III promoters and terminators. Applicants acknowledge the U6-type RNA polymerase promoter to be old. It would have been obvious to one of ordinary skill in the

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art at the time the invention was made to substitute any known promoter (i.e. the admittedly old U6-type promoter) for the promoter in the vector of either primary reference in order to produce large amounts of antisense oligonucleotides.

Claims 27 and 28 are rejected under 35 U.S.C. § 103 as being unpatentable over either one of Jennings et al or Sullenger et al in view of Lyamichev et al. Each of Jennings et al (e.g., Figure 3) and Sullenger et al (e.g., Figure 2) discloses nucleic acid blots.

Lyamichev et al teaches the electrophoresis of triple stranded nucleic acids, one strand of which is labeled. It would have been obvious to one of ordinary skill in the art at the time the invention was made to blot DNA or RNA in the manner disclosed in either one of the primary references and to detect the resulting separated and blotted nucleic acids with a labeled nucleic acid in a triplex formation as is disclosed in Lyamichev et al in order to detect nucleic acids that contain specific sequences.

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